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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,949	04/19/2001	Jean-Louis Excoffier	01-02 US	4507

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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,949

Applicant(s)

EXCOFFIER, JEAN-LOUIS

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 30-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 1 Sheet.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Attachment for PTO-948.

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DETAILED ACTION

APPLICANT'S ELECTION

Applicant's election of Group I (claims 1-29 and 43; drawn to a method, system, and computer usable medium for classifying chromatograms) in Paper No. 6, filed 07 October 2002, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03). Claims 30-42 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

CLAIMS UNDER EXAMINATION

Claims 1-29 and 43 are herein under examination.

OBJECTION BY DRAFTSMAN

Applicant is hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification applicant is required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

SCOPE OF ENABLEMENT

Claims 1-29 and 43 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of classifying a chromatogram, does not reasonably provide enablement for all forms of adjustment to chromatogram data, all forms of reducing chromatogram data to a data set, and all equations for analysis as encompassed by applicant. Applicant's enablement is limited to "adjusting data in the first and second regions of interest comprising centering an analysis window around one or more trace features in a given region of interest" (instant claim 4); "reducing the first and second chromatogram data to the first and second data sets: comprising determining an integral of the first and second chromatogram data and plotting against a time axis; determining a set of time points; and forming arrays of data set values based upon the set of time points and corresponding integral values for the set of time

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points" (instant claim 9); "Similarity Equation" (Eq. 5); "Dissimilarity Equation" (Eq. 6); and "Distance Equation" (Eq. 7) as indicated on pages 11-12 of the specification. The original disclosure lacks guidance (other than that stated above) to perform the acts/steps of "adjusting" (i.e. centering an analysis window arbitrarily) and "reducing" (i.e. data set values based upon an arbitrary value rather than time point). The disclosure presents specific equations for determining the degree of "similarity", "dissimilarity", and "distance", however, fails to provide guidance on how to perform other "similarity", "dissimilarity", and "distance" determinations as broadly encompassed by applicants' claim language. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29 and 43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1, 19, 43, and all claims dependent therefrom are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "A method of classifying chromatograms", however the claim recites a final step of "comparing the first data set and the second data set". There is no indication that chromatograms are intended to be classified as resuscitated in the preamble.

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While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when the chromatograms are classified. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Claims 1 (lines 5 and 9) and 43 (lines 7 and 11) recites the phrase "consistent positioning" which is vague and indefinite. The limitation of "consistent positioning" fails to provide active steps to be performed to meet the limitation of the claim. Clarification is required, via clearer claim wording.

Claim 3 (lines 2 and 3) recites the phrases "identifying a first chromatogram region" and "identifying a second chromatogram region" which are confusing. It is unclear at which step of claim 1 the above steps are to be performed (i.e. before comparing the first data set and the second data set or after). Clarification, via clearer claim wording is required.

Claims 6 (line 1), 20 (line 1), and all claims dependent therefrom recites the phrase "bad data"/"bad data filter" which is vague and indefinite. It is acknowledged that the specification (page 6, lines 16-30) describes "bad" as flawed data ("a peak that exceeds a threshold characteristic") and that a "bad data filter could be employed to determine if a particular chromatographic trace corresponds to flawed data". However, the disclosure fails to provide further meaning or limitation to the term "threshold characteristic". Thus, given the broad concepts provided for by the disclosure, it is unclear what applicant refers to as "bad or flawed data". Clarification of the metes and bounds of this limitation, via clearer claim language, is required.

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Claim 10 (line 2) and all claims dependent therefrom recites the phrase "selecting a reference chromatogram" which is confusing. It is unclear at which step of claim 1 the reference chromatogram is to be selected (i.e. before receiving a first chromatogram data or after).

Clarification, via clearer claim wording is required.

Claims 12 (line 1) and 13 (lines 1-2) recite the phrase "other chromatograms" which is vague and indefinite. The method step of claim 1 fails to indicate that "other chromatograms" are compared, rather the first data set and the second data set are compared. Clarification of the metes and bounds, via clearer claim language, is required.

LACK OF ANTECEDENT BASIS

Claim 4 and all claims dependent therefrom recites the phrase "first and second regions" in line 1. There is a lack of antecedent basis for this limitation in claim 1 from which claim 4 depends to.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-29 and 43 are rejected under 35 U.S.C. § 102 (b) as being unpatentable over Bogden et al. (U.S. Patent Application Number 6,195,449 B1).

Bogden et al. describes a method and apparatus for the analysis of data files derived from fluorophore emissions (i.e. chromatograms) detected during observation of fluorophore labeled nucleotide polymers (i.e. sequencing) (instant claims 1, 18, 19, and 43; Abstract and Column 9,

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lines 44-46). The inventors apply techniques used in processing speech signals to analyzing chromatogram data (Column 5, lines 35-38). Initially, data files (i.e. chromatogram) are imported into the memory of a computer (instant claims 3, 4, 23, and 27; Columns 9-10, lines 38-67 and 1-42, respectively). Followed by the extraction of vectors from peak features (i.e. peak spacing, height, area under the peak, time for evolution and devolution of the peak, occurrence of a secondary peak) of the chromatographic data (instant claims 5, 7-9, 17, 21, and 24-26; Columns 10-12), wherein it is optionally provided that prior to peak feature extraction chromatogram signals are corrected for certain distortions such as peak clipping and contextual influences (similar to the removal of noise; i.e. baseline correction) (instant claims 2, 6, 20, and 22; Column 10, lines 54-58). The chromatographic data is comparative analyzed (Columns 5-6, lines 65-67 and 1-20, respectively; and Columns 12-14). Optionally, data maybe designated as "sample" or "reference" (instant claims 10-13; Column 6, lines 49-51). Bogden et al. provides for an "interactive analysis interface" which comprises a display and capabilities for viewing similarities and dissimilarities among chromatographic data (instant claims 14-16, 28, and 29; Columns 14-15, lines 29-67 and 1-29, respectively). Thus, Bogden et al. clearly anticipates the claimed invention.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

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1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *December 26, 2002*

Examiner Initials: *CSM*

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